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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/091,935 | SHEFER ET AL. | |
| | Examiner | Art Unit | |
| | Isis A. Ghali | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 March 2007* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,4,5,7-33,35,36,38-42 and 47-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7-33,35,36,38-42 and 47-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 03/26/2007.

Claims 2, 3, 6, 34, 37, and 43-46 have been canceled, and claims 48 and 49 have been added.

Claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47-49 are pending and included in the prosecution.

**The following rejections have been overcome by virtue of applicants' amendment and remarks:**

(A) The rejection of claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47 under 35 U.S.C. 112, second paragraph as being indefinite.

(B) The rejection of claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47-49 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

**The following new ground of rejection is necessitated by applicants' amendment:**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:—

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 33, 35, 36, and 48-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps between applying the patch to the skin and rinsing/removing the patch from the skin because as such the patch is not used for delivering therapeutic agents to the user.

**The following rejections have discussed in details in the previous office action, and are maintained for reasons of record:**

***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-50 of copending Application No. 10/376,736. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: the present claims and the conflicted copending claims are directed to patch and method of its use, wherein the patch comprises single matrix layer comprising bioadhesive water-soluble polymer selected from the group consisting of polyvinyl pyrrolidone (PVP), polyvinyl alcohol (PVA), modified starch derivatives, and hydrolyzed starches, and wherein the matrix dissolves or disintegrates in presence of water.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The examiner acknowledges Applicants' statement that "since neither the claims of the present application nor the copending application have yet been finalized, Applicant is unable to respond at this time. Applicant reserves the fight to rebut the

provisional rejection, at such time as these claims are otherwise in condition for allowance and a rational comparison of the two sets of claims can be made."

However, the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only remaining rejection in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other applicant into a double patenting rejection at the time the one application issues as a patent.

## *Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 4, 5, 13-15, 17, 18, 21, 27, 29-33, 42, 47, 48 are rejected under 35 U.S.C. 102(b) as being anticipated by 5,780,047 ('047).

The present claims 1 and 42 are directed to polymeric layer of film forming polymer selected from the group consisting of: maltodextrin, polyvinyl alcohol, polyvinyl pyrrolidone, modified starch derivatives, starch derivatives, modified starches, hydroxypropyl cellulose, and hydrolyzed starch and a combination thereof. Claims 33 and 35 are directed to method of using the polymeric layer.

US '047 disclosed patch comprises water-soluble adhesive sheet that can be applied to the skin and have adhesiveness such that if falls off from the skin upon wetting (abstract; col.2, lines 62-64; col.11, lines 13-15). The water-soluble polymers included polyvinyl pyrrolidone and pullulan, i.e. modified starch (col.3, lines 5-8). The adhesive sheet material further comprises glycerol and propylene glycol claimed by applicants in claim 21 as solubilizers (col.5, lines 4-12). The patch of polymer sheet further comprises active agents including drugs, vitamins, lanolin (moisturizer claimed by claims 14 and 15), vitamins, antiseptic, anti-inflammatory agent, sodium salicylate, amino acids, menthol and capsaicin (col.6, lines 59-64; col.7, lines 61-63; col.8, lines 7-10, 22; col.10, line 25). The adhesive sheet comprises fats and oils that read on permeation enhancer claimed by claim 17 (col.7, lines 38-52). The thickness of the water-soluble adhesive sheet is preferably from 20-1,000 μm, i.e. 0.02 to 1 mm as claimed by claim 29 (col.5, lines 29-33). The active ingredients are inherently uniformly distributed throughout the matrix as implied by the reference disclosure that the ingredients and the polymer matrix are mixed together (col.11, line 65).

***Response to Arguments***

7. Applicant's arguments filed 03/26/2007 have been fully considered but they are not persuasive. Applicants argue that the '047 teaches a patch comprising an adhesive sheet containing an adhesive that enables the patch to be attached to the skin, and the patch of the '047 patent requires a protective sheet to prevent the adhesive patch from sticking to the fingers. Applicants' argue that '047 does not teach a patch that, upon wetting, becomes tacky to support adhesive application to the skin and US'047 is adhesive at the start due to an adhesive layer rather than becoming tacky and adhesive after wetting. Thus, '047 does not teach every limitation of the claims.

In response to this argument, applicant's attention is directed to the scope of present claims 1 and 42 that are directed to polymeric layer of film forming polymer selected from the group consisting of: polyvinyl alcohol, polyvinyl pyrrolidone, starch derivatives, starch or hydroxypropyl cellulose, and claims 33 and 35 that are directed to method of using the polymeric layer. All the elements of the composition claims are disclosed by the references, and the steps of the method claims that include applying the patch, and removing the patch by using water are disclosed by the reference. US '407 disclosed adhesive sheet made from the same material as the present claims including cellulose derivatives and polyvinyl alcohol, and further disclosed that the adhesive is water soluble polymer (col.2, lines 53-58, 65-67). The reference clearly disclosed that the patch is solubilized in water (col.11, lines 39-42). The reference disclosed that the adhesiveness of the adhesive sheet can be controlled by adjustment of its water content, and when dry it loses its adhesiveness and with adding water it retain its adhesiveness (col.4, lines 60-65), and this reads on the claims' limitation of

"the patch becomes tacky after wetting". In any events, such properties of the adhesive are inherent to specific adhesive, and properties and compounds are inseparable. The expression "comprising" of the claims' language permits the presence of protective sheet, and applicant's invention includes a protective sheet.

8. Claims 1, 4, 5, 9, 10, 12, 14,15, 17, 18, 21-24, 27, 29-33, 42, 47, 48 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,497,887 ('887).

The present claims 1 and 42 are directed to polymeric layer of film forming polymer selected from the group consisting of: maltodextrin, polyvinyl alcohol, polyvinyl pyrrolidone, modified starch derivatives, starch derivatives, modified starches, hydroxypropyl cellulose, and hydrolyzed starch and a combination thereof. Claims 33 and 35 are directed to method of using the polymeric layer.

US '887 disclosed polymeric membrane in form of matrix dissolvable upon wetting and can be used to deliver biologically active agents to the skin (abstract; col.3, line 45). The membrane permits sustained delivery of active ingredients to the skin and does not have to be peeled or washed off the skin, but simply dissolve (col.6, lines 11-16). The membrane is made of water-soluble polymers such as starches (col.1, lines 60-67; col.2, lines 21-34). The membrane further comprises additional film forming polymers such as hydroxypropyl cellulose and polyvinyl pyrrolidone and polyvinyl alcohols (col.3, lines 18-30). The active agents included in the membrane include moisturizers, salicylic acid, vitamins, whitening agents, antiseptics, anti-inflammatory agents, antihistamine, anti-aging agents, tanning agents (col.5, lines 10-20, 23-25, 33-

40, 44, 59-67; col.6, lines 1-4). The membrane further comprises glycerin, that reads on solubilizers and permeation enhancers, and amino acids, that reads on claim 47 (col.3, lines 9-12). The membrane comprises polyphenols, i.e. antiseptic (col.6, line 26). The membrane may be wetted before use or applied to wetted skin (col.4, lines 63-67). The membrane has a thickness 0.1 to 1.5 mm and its shape and size are varied according to the intended use (col.3, lines 50-56). The active ingredients are inherently uniformly distributed throughout the matrix as implied by the reference disclosure that the ingredients and the polymer matrix are mixed together (col.6, line 47).

***Response to Arguments***

9. Applicant's arguments filed 03/26/2007 have been fully considered but they are not persuasive. Applicants traverse this rejection by arguing that '887 membrane cannot dissolve in water or disintegrate because it is formed of cross-linked polymers and even lightly cross-linked polymers swell extensively ad do not dissolve. Applicants are referring to “Textbook of Polymer Science”, page 151, first and third paragraphs for disclosing that this fact is fundamental to the art of polymer chemistry, as is clear by its inclusion in the Textbook of Polymer Science. US '887 merely describes a dry membrane that is applied to the skin and becomes and remains a swollen gel upon contact with water, remaining in place in gel form as it is rubbed into the skin. US'887 never teaches that the membrane dissolves into water or disintegrates. Thus, '887 does not teach each and every limitation of the claims.

In response to this argument, applicant's attention is directed to the scope of present claims 1 and 42 that are directed to polymeric layer of film forming polymer selected from the group consisting of: polyvinyl alcohol, polyvinyl pyrrolidone, starch derivatives, starch or hydroxypropyl cellulose, and claims 33 and 35 that are directed to method of using the polymeric layer. All the elements of the composition claims are disclosed by the references, and the steps of the method claims that include applying the patch, and removing the patch by using water are disclosed by the reference. US '887 clearly teach at col.6, lines 12-16, that "the film does not have to be peeled off after use, but simply dissolves". Therefore, all the elements of the claims are disclosed by the reference. The claims' language does not exclude cross-linked polymers. The "Textbook of Polymer Science", page 151, 3rd paragraph, does not exclude dissolution and disintegration of the cross-linked polymers. Properties of the adhesive are inherent to specific adhesive, and properties and compounds are inseparable including tackiness and dissolution.

## *Claim Rejections - 35 USC § 103*

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 7, 8, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '047 in view of US 2003/0027833 ('833).

The teachings of US '047 are discussed above. However, US '047 does not teach the specific antiseptics claimed by claims 7 and 10 and specific antibiotics claimed by claim 8.

US '833 discloses pharmaceutical composition in the form of single adhesive polymeric layer, film or matrix that deliver local anesthetic agent to the skin (abstract; page 2, paragraphs 0014-0017; page 9, paragraph 0091). The polymeric layer is water-soluble and can be removed easily by application of water, and selected from PVP, PVA, hydroxypropyl cellulose, starch and starch derivatives with a pharmaceutically active agent homogenously admixed therein with a permeation enhancer (page 2, paragraphs 0021, 0023; page 6, paragraph 0070, 71; page 7, paragraphs 0077, 0078). The polymeric layer further comprising additional active agent with the preferred

additional active agents including bactericidal agent selected from iodine, silver, mercury compounds, phenol and chlorhexidine (page 4, paragraph 0051) and antibiotic including tetracycline (page 4, paragraph 0052).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin including antiseptic as disclosed by US '047, and select the antiseptic from iodine, silver, mercury compounds, phenol, chlorhexidine, and/or antibiotic including tetracycline as disclosed by US '833, motivated by the teaching of US '833 that such antiseptics and antibiotics are preferred to be included in the matrices applied to the skin, with reasonable expectation of having topical film of water soluble polymer to deliver active agents to the skin including iodine, silver, mercury compounds, phenol, chlorhexidine, and/or tetracycline that delivers such ingredients to skin of the patient in need of such treatment wherein the film dissolves afterward without the need of the pain of peeling off of the film from the skin.

13. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '887 in view of US '883.

The teachings of the references are discussed above. However, US '887 does not teach the specific antiseptics claimed by claims 7 and specific antibiotics claimed by claim 8, that are taught by US '833.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active

agents to the skin including antiseptic as disclosed by US '887, and select the antiseptic from iodine, silver, mercury compounds, chlorhexidine, and/or antibiotic including tetracycline as disclosed by US '833, motivated by the teaching of US '833 that such antiseptics and antibiotics are preferred to be included in the matrices applied to the skin, with reasonable expectation of having topical film of water soluble polymer to deliver active agents to the skin including iodine, silver, mercury compounds, chlorhexidine, and/or tetracycline that delivers such ingredients to skin of the patient in need of such treatment wherein the film dissolves afterward without the need of the pain of peeling off of the film from the skin.

***Response to Arguments***

14. Applicant's arguments filed 03/26/2007 have been fully considered but they are not persuasive. Applicants hereby repeat the argument with regard US '407 and US '877. Applicants further argue that US '833 does not cure the defects of US '407 and US '887 because it does not teach the missing limitation and furthermore because US '833 teaches two different embodiments, one embodiment is a liquid or gel that forms a film only after application to the body, and the other embodiment is multilayered, so the embodiments of US '833 are outside the limitations of the claims. The combination of prior art references fails to teach each of the limitations incorporated into the claims, no prima facie of obviousness has been presented.

Regarding US '407 and US '887, the examiner's hereby repeats response in sections 7 and 9 of this office action. Regarding US '833, the reference is relied upon for

the solely teaching of specific antiseptic and antibiotics that claimed by claims 7, 8, and 10, and their suitability for topical formulation. In response to applicant's argument that embodiment of US '833 are outside the claims' limitations, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one having ordinary skill in the art at the time of the invention would have been motivated to incorporate iodine, silver, mercury compounds, phenol, chlorhexidine, and/or antibiotic including tetracycline in the topical film disclosed by US '407 or US '887 that suggested incorporation of active ingredients in the topical formulation, and motivated by the teaching of US '833 that such antiseptics and antibiotics are preferred to be included in the matrices applied to the skin, with reasonable expectation of having topical film of water soluble polymer to deliver active agents to the skin including iodine, silver, mercury compounds, phenol, chlorhexidine, and/or tetracycline that delivers such ingredients to skin of the patient in need of such treatment wherein the film dissolves afterward without the need of the pain of peeling off of the film from the skin. Therefore, the combination of the references teaches the limitation of the claims, and the invention as whole as far as claims 7, 8, and 10 are taught by the combination of US '407 and US '833.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

15. Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '047 or US '887.

The teachings of US '047 and US '887 are discussed above. However, the references do not teach the specific anti-inflammatory ibuprofen as claimed in claim 11 as an active agent.

It is within the skill in the art to determine the species of anti-inflammatory agent to be delivered to the skin by the water soluble polymer film disclosed by the references according to the specific patient need and intended use, since both references disclosed anti-inflammatory agent are suitable for delivery from such films. Applicants failed to show superior and unexpected results obtained by using the water-soluble film to deliver ibuprofen in particular. Therefore, ibuprofen claimed by claim 11 does not impart patentability to the claims, absent evidence to the contrary.

16. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '047 in view of US '887.

The teachings of US '047 and US '887 are discussed above. However, US '047 does not teach antihistamine as claimed in claim 12 that is taught by US '887.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin as disclosed by US '047, and replace the active agent by antihistamine as disclosed by US '887, motivated by the teaching of US '887 that such antihistamine can be delivered by dissolvable film, with reasonable expectation of having topical film of water soluble polymer to deliver antihistamine to the skin of the patient in need of such treatment wherein the film dissolves afterward without the need of the pain of peeling off of the film from the already compromised skin.

17. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '887 in view of US '047.

The teachings of US '887 and US '047 are discussed above. However, US '887 does not teach menthol or capsaicin as claimed in claim 13 that is taught by US '047.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin as disclosed by US '887, and add menthol or capsaicin as disclosed by US '047, motivated by the teaching of US '047 menthol provides cooling effect to the skin and capsaicin warming effect to the skin, with reasonable expectation of having

topical film of water soluble polymer comprising menthol or capsaicin to provide cooling or warming effect to the skin according to the specific patient need and wherein the film dissolves afterward without the need of the pain of peeling off of the film from the skin.

***Response to Arguments***

18. Applicant's arguments filed 03/26/2007 have been fully considered but they are not persuasive. Applicants argue that US '406 and US '887 and their combination are defective in failing to teach a membrane having either (1) the polymeric matrix layer of the patch that dissolves in water or disintegrates upon rinsing the patch with water or (2) a patch that becomes tacky after wetting, so that the adhesive property of the tacky patch adheres the patch to the skin, no prima facie showing of obviousness has been presented

In response to this argument, and as discussed in sections 7 and 9 of this office action, US '407 and US '887 anticipate at least the generic claims 1, 33, and 42, because the properties of the adhesives such as tackiness and adhesiveness are inherent for specific adhesive. Applicants failed to show unexpected results obtained from using the specific anti-inflammatory disclosed by claim 11. The combination of US '407 and US '887 would have suggested to one having ordinary skill in the art at the time of the invention to replace the active agent disclosed by US '407 by antihistamine as disclosed by US '887, motivated by the teaching of US '887 that such antihistamine can be delivered by dissolvable film, with reasonable expectation of having topical film of water soluble polymer to deliver antihistamine to the skin of the patient in need of

such treatment wherein the film dissolves afterward without the need of the pain of peeling off of the film from the already compromised skin. The combination of US '407 and US '887 would have suggested to one having ordinary skill in the art at the time of the invention to add menthol or capsaicin disclosed by US '407 to the topical formulation of US '887, motivated by the teaching of US '047 menthol provides cooling effect to the skin and capsaicin warming effect to the skin, with reasonable expectation of having topical film of water soluble polymer comprising menthol or capsaicin to provide cooling or warming effect to the skin according to the specific patient need and wherein the film dissolves afterward without the need of the pain of peeling off of the film from the skin.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

19. Claims 9, 19, 20, 22-24, 26, 35, 36, 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '047 in view of US 2001/0007671 ('671).

The teachings of US '047 are discussed above.

However US '047 does not teach the salicylic acid as claimed in claim 9, the transparent polymeric film as claimed in claim 19 or colored as claimed in claim 20, the cosmetics claimed in claims 22-24, the effervescent claimed in claim 26, or the period of applying the film as claimed 35, and 36.

US '671 teaches a cosmetic, pharmaceutical, or dermatological patch for application of active agent to the skin (abstract; page 1, 0012, 0015). The patch imparts great softness, freshness and coolness and easily manipulated during application and removal from the skin (page 1, paragraph 0007). The patch includes a water-polymer matrix layer comprising an active agent and polymer (Figures 1; page 2, 0017, 0018, 0024, 0035; page 3, 0046; page 7, claim 15; page 8, claims 67-70). The active agents include moisturizers, bleaching agents (depigmentation agents), anti-acne agents, anti-aging agents, anti-wrinkle agents, anti-inflammatory agents, softeners, keratolytic agents, etc. (page 3, 0046, 0047). The patch is transparent or colored (page 2, 0020; page 3, 0050). The composition includes acetylsalicylic acid (aspirin) (page 3, 0047). The composition comprises sodium carbonate and sodium bicarbonate (page 3, 0043). The patch is applied to the skin from about few seconds to about few days (page 1, 0015). The composition further comprises salicylic acid, which is a keratolytic agent (page 3, 0048; page 8, claim 60).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin as disclosed by US '047, and add effervescent material and select the active agent suitable for delivery to the skin or across the skin according to the

specific condition to be treated, and made the film colored or transparent and adjust the time of application of the film as disclosed by US '671, motivated by the teaching of US '671 that such ingredients when applied topically impart great softness, freshness and coolness to the skin, with reasonable expectation of delivering wide varieties of beneficial active agent to the skin from colored of transparent film for the desired period of time wherein the film dissolves afterward without the need of the pain of peeling off of the film from the skin.

20. Claims 19, 20, 26, 35, 36, 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '887 in view of US '617.

The teachings of US '887 and US '617 are discussed above. However US '887 does not teach the transparent polymeric film as claimed in claim 19 or colored as claimed in claim 20, the effervescent claimed in claim 26, or the period of applying the film as claimed 35, and 36, which all taught by US '617.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin as disclosed by US '887, and add effervescent material, and made the film colored or transparent and adjust the time of application of the film as disclosed by US '671, motivated by the teaching of US '671 that such film when applied topically impart great softness, freshness and coolness to the skin, with reasonable expectation of delivering beneficial active agent to the skin for the desired period of time from

colored of transparent film wherein the film dissolves afterward without the need of the pain of peeling off of the film from the skin.

***Response to Arguments***

21. Applicant's arguments filed 03/26/2007 have been fully considered but they are not persuasive. Applicants hereby repeat the argument regarding US '407 and US '887. Applicants further argue that the Examiner has not presented rational grounds to show that one skilled in the art would have been motivated to combine the teachings of the references. The Examiner stated that one of ordinary skill in the art would have been motivated by the teaching of US'671 that the active ingredients, effervescent or coloring agent when applied topically impart great softness, freshness and coolness to the skin. However, US'671 does not teach that those ingredients impart softness, freshness and coolness. Instead, US'671 teaches that softness, freshness and coolness is imparted by patches with high water content and that this also makes the patches easily manipulated during application and removal and that if active agents are incorporated into such patches, these characteristics can be enjoyed during the application of the active agents.

In response to this argument, it is established that in considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be

expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

22. Claims 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '047 or US '887, each in view of US 6,419,935 ('935).

The teachings of US '047 and US '887 are discussed above. However, US '047 and US '887 do not teach dihydroxyacetone claimed by claim 25 or the size of the film as claimed by claim 28.

US '935 teaches cosmetic skin treatment method includes providing a patch with good adhesiveness without drying the skin that includes polymeric matrix that includes at least one cosmetically active compound (abstract; col.1, lines 43-57; col.2, lines 49-57; col.9, lines 66-67). The patch is configured to adhere to the dry skin and to the moistened skin to provide treatment and cleansing the skin (abstract; col.2, lines 1-3, 57-59; col.3, lines 12-14). The patch provides treatment for time ranging from 5 minutes

to 60 minutes (col.2, lines 8-12; col.4, lines 64-67). The cosmetically active compounds to be incorporated in the matrix include dihydroxyacetone (col.5, lines 62-65). The patches are cut to shapes designed to fit on various parts of the body and the preferred size ranges from 1 $cm^2$ to 30 $cm^2$ (col.9, lines 6-18). The polymeric matrix forms a layer having a thickness of 0.2 mm (col.9, lines 66-67).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin as disclosed by US '047 and US '887, and use the film to deliver dihydroxyacetone to the skin, and select the specific size of the film according to the area to be treated as disclosed by US '935, motivated by the teaching of US '935 that dihydroxyacetone is a tanning agent suitable for topical delivery from films and such a size of patch is suitable size, with reasonable expectation of delivering dihydroxyacetone to the skin from a film that dissolves afterward without the need of the pain of peeling off of the film from the skin.

***Response to Arguments***

23. Applicant's arguments filed 03/26/2007 have been fully considered but they are not persuasive. Applicants herby incorporate the argument regarding US '407 and US '887. Applicants further argue that the combination of prior art references is defective in failing to teach each of the limitations incorporated into the claims, no prima facie showing of obviousness has been presented.

In response to this argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one having ordinary skill in the art at the time of the invention would have been motivated to deliver dihydroxyacetone to the skin in the film disclosed by Us '407 or US '887, and select the specific size of the film according to the area to be treated as disclosed by US '935, motivated by the teaching of US '935 that dihydroxyacetone is a tanning agent suitable for topical delivery from films and such a size of patch is suitable size, with reasonable expectation of delivering dihydroxyacetone to the skin from a film that dissolves afterward without the need of the pain of peeling off of the film from the skin.

24. Claims 16 and 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '047 and US '887, each in view of US 5,667,798 ('798).

The teachings of US '047 and US '887 are discussed above. However, the references do not teach microencapsulation of the active ingredients as claimed by claims 16, 38, 39 and 41, or their material as hydrophobic as claimed in claim 40.

US '798 teaches transdermal device comprises matrix comprising active agent dispersed in microencapsulated form to control the release of the active agents

(abstract; col.1, line 67-col.2, line 2). The drug release into the matrix is controlled by selecting the microcapsules as hydrophilic or hydrophobic (col.2, lines 9-15).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin as disclosed by US '047 and US '887, and further microencapsulate the active agent in hydrophobic material as disclosed by US '798, motivated by the teaching of US '798 that microcapsules and their material play role in controlling the release of the active agent, with reasonable expectation of having topical film of water soluble polymer comprising microencapsulated active agents to be delivered to the skin of the used in a controlled release manner effectively.

***Response to Arguments***

25. Applicant's arguments filed 03/26/2007 have been fully considered but they are not persuasive. Applicants herby incorporate the argument regarding US '407 and US '887. Applicants further argue that the combination of prior art references is defective in failing to teach each of the limitations incorporated into the claims, no prima facie showing of obviousness has been presented.

In response to this argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir.

1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one having ordinary skill in the art at the time of the invention would have been motivated to microencapsulate the active agent in hydrophobic material as disclosed by US '798, motivated by the teaching of US '798 that microcapsules and their material play role in controlling the release of the active agent, with reasonable expectation of having topical film of water soluble polymer comprising microencapsulated active agents to be delivered to the skin of the used in a controlled release manner effectively.

## *Conclusion*

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
Art Unit 1615

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ISIS GHALI
PRIMARY EXAMINER